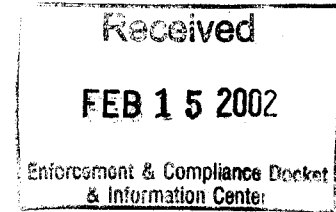




January 28, 2002

United States Environmental Protection Agency
Enforcement and Compliance Docket and Information Center
Mail Code 2201 A
Attn: Docket Number EC-2000-007
1200 Pennsylvania Avenue NW
Washington, DC 20460



Re: Proposed Rule - Cross-Media Electronic Reporting and Record Keeping Rule

On behalf of Packaging Corporation of America (PCA), this document is respectfully submitted as comment on the referenced proposed rule. PCA is among the largest manufacturers of containerboard and corrugated packaging products in the United States and is headquartered in Lake Forest, Illinois. Our manufacturing operations include four containerboard mills and 65 corrugated products plants. These operations, particularly the containerboard mills, would be regulated and significantly impacted, under the proposed rule. Details of our concerns are described below.

1. The CROMERRR Recordkeeping requirements do not appear to be voluntary.

Although EPA represents otherwise, the rule will be mandatory for almost all operations required to keep EPA compliance records. As proposed, the term "electronic record" is broadly defined, and would appear to include both records kept electronically at all times and those created or stored temporarily on a computer, then printed out and kept as a paper record. Electronic record is defined as: any combination of text, graphics, data, audio, pictorial, or other information represented in digital form that is created, modified, maintained, archived, retrieved or distributed by a computer system. Therefore, any record that is the result of any component of digital data input, or of data that had at any point passed through a computer system, would be considered an "electronic record" and subject to the requirements. As a result, all computer systems involved in creating, modifying, maintaining, archiving, retrieving, or distributing any bit of electronic information that contributed to the resulting record would be subject to the requirements of the rule.

For example, Distributive Control Systems (DCS) generate a wide range of process and productivity data at our mills. Some of these "process" data outputs also may support compliance with a permit limit, such as a limit on production per machine or per day. Normally, we would consider the DCS to be part of the input system (along with digital transmitters on modern instrumentation, etc.) rather than part of the electronic record. It generally provides short term transient data that must then be archived on another

system or is lost. However, the EPA definition, as proposed, would include this "created" data as an electronic record, thereby classifying the DCS as part of the "electronic recordkeeping system" and subject to the criteria of the rule.

A Process Information System (PI) typically collects, summarizes, and stores the outputs from the DCS, including information that may then be transferred, either "real time" or "on demand," to another format for compliance reporting and recordkeeping. In the former case the PI system serves as a "transmission" system for the data that will ultimately become a compliance record. Again, based on the inclusive EPA definition of "electronic record", the PI system would be considered a regulated electronic recordkeeping system, although another system might be used "on top" of the PI system to actually report and store the electronic compliance data, or to print the data for reporting or storage. Where a PI system serves as a transmission system and is not the primary record, i.e., there is a secondary electronic record or a timely paper record has been made from PI data, PI systems should not be included as a regulated electronic record under this rule.

With the ever increasing monitoring requirements under environmental regulations, the "paper only" recordkeeping system, as defined under the proposal, that would be required to avoid regulation under this proposed rule is not practical at most modern manufacturing locations. For all practical purposes, the recordkeeping requirements proposed would be mandatory. The rule must be revised to clarify and limit applicability only to systems whose function is to actually store electronic compliance records over time and to report compliance information required under EPA rules, and specifically to exclude other related systems, such as Distributive Control Systems and Process Information Systems that are used as transmission systems rather than the electronic record for reporting and storage.

Furthermore, the rule would appear to prohibit any use of computers to keep mandated records until EPA announces that it's okay. EPA must recognize that computers have been used for over 20 years to generate, track, summarize, and store data that might be used to support or generate compliance reports or records.

2. EPA has grossly underestimated the cost of compliance to industry, which could exceed \$1,000,000 for a large industrial facility.

Due to the above-cited non-voluntary nature of the proposal, its broad inclusion of information and data storage systems, and the stringent anti-fraud provisions that current computer systems lack, EPA's cost estimates for this rule are likely to be underestimated by orders-of-magnitude. The proposal estimates an annual average cost of \$40,000 per facility for implementation of an electronic recordkeeping system. A similar rule passed by FDA (21 CFR Part 11), which after which EPA's rule was modeled and to which it is almost identical, has reportedly cost many drug companies

over \$100 million each to comply. FDA had initially estimated minimal to no net cost to the regulated industry. We estimate that the rule could cost upwards of \$1,000,000 to implement at each of our containerboard mills if adopted as proposed.

Furthermore, EPA apparently did not conduct an adequate Risk Assessment and Cost/Benefit Analysis on the need for such stringent anti-fraud provisions, as directed by OMB guidance issued under the Government Paperwork Elimination Act (GPEA). EPA must complete (or revise) their Risk Assessment and Cost/Benefit Analysis to better represent the cost of compliance with the rule.

3. Technical Feasibility Issues

- **Lack of Compliant Software or Systems:** We know of no "Off the shelf" software available that will comply with all of the proposed criteria, particularly for DCS systems and for spreadsheet database systems, both integral parts of most electronic systems as they appear to be defined under the proposed rule definition. If this turns out to be the case, then software would have to be written to meet the regulation requirements. Our process information systems (DCS and PI) would require extensive review and modification of both software and hardware (cabling, transmitters, memory, interface technology, etc.). Compliance criteria must be achievable with currently available technology. Furthermore, the requirement for time stamping and traceability of changes should apply only to the raw data storage and not to calculated data in reports and spreadsheets. The latter is no different than a paper report prepared using raw data and a calculator, and as noted above there is no current spreadsheet software to our knowledge that could comply with a time stamp requirement.
- **Transferability:** How do you transfer data to an unknown system? How can we ensure that the data will be transferable to software that has not yet been developed? The requirement for "transferability to new systems" must be deleted from the proposal or it will be a major feasibility issue. The obligation should be limited to the ability to reproduce the data on one's own system when demanded by EPA. That is, one must maintain a system to be able to retrieve data for the duration required under the applicable rule, typically 5 years.
- **Data Compression:** Process data collection systems like DCS and PI use data compression techniques that record/store a value and then will only store another value if a change over and above a set significance level has occurred or a certain time interval has elapsed. When recalled, the interim data is "recreated" between the data points based on that significance level or time interval, but the "real" data, micro-second by micro-second, is not actually stored. To do so would require enormous databases and thus enormous servers/data storage capability. This feature is not unique to PCA, but rather is common to all, or at least most, systems that store large volumes of data and use data compression to do so.

Page 4 of 4

EPA must provide an allowance for data compression techniques, or clarify that these systems are not covered under the rule.

In closing, we urge EPA to withdraw this rule until full consideration and revision may be made to address the many significant problems the rule will present to the regulated industry. We appreciate the opportunity to provide comment on this proposed rule.

Sincerely,

A handwritten signature in black ink that reads "Ron Reynolds". The signature is written in a cursive style with a large, sweeping "R" and a long, horizontal flourish at the end.

Ronald E. Reynolds
Director of Environment, Health & Safety
Packaging Corporation of America

Bc: B. Sorensen
R. Brown
G. Holton
R. Holland
J. Piotrowski